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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,339	12/31/2003	Larry Augsburger	UMB-004US3	9882

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EXAMINER	
SILVERMAN, ERIC E	

ART UNIT	PAPER NUMBER
1618	

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12/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,339	AUGSBURGER ET AL.	
	Examiner	Art Unit	
	ERIC E. SILVERMAN	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' reply, containing arguments and claim amendments, was entered on 9/21/09. A transmittal letter and new power of attorney were received on 11/12/2009.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim1-11 remain rejecteded on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-30 of U.S. Patent No. 5,780,055 in view of Botzolakis for reasons of record and those discussed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Habib in view of Botzolakis for reasons of record and those discussed below.

Response to Arguments

1. The anticipation rejections are withdrawn for reasons other than those in Applicants' comments

Applicants' arguments regarding the anticipation rejections are not found persuasive. The Examiner rejects the argument that oven-drying does not produce porous materials as that term is defined in this Application.

The rejection is withdrawn because a review of the evidence of record indicates that oven drying produces cushioning materials that are different in structure than materials produced by freeze-drying (lyophilizing). Habib at col. 2 and in the Examples indicates that the method of drying imparts important differences on the structure of the final product. Freeze-drying produces a product with less volume loss compared to the volume of wet product than other methods; freeze-drying also produces products that are more compactable and form harder tablets than other methods.

Based on the evidence in Mount and Botzolakis it is unreasonable to conclude, as Applicants do, that oven-drying or table-drying produce materials that are not porous. However, Habib indicates that the pore structure produced by freeze drying is different than that produced by other drying methods. That structural difference makes a holding of anticipation over the art of record inappropriate.

2. The rejections for obviousness and non-statutory double patenting are proper

The obviousness rejection under section 103(a) and the non-statutory double patenting rejection are based on the prior art, and Applicants' argue the two rejections together. Therefore this response treats the two rejections together.

A. Habib does not teach away from a combination with Botzolakis

Applicants' first argument is that Habib teaches away from a combination with Botzolakis. Applicants' believe this to be true because Botzolakis uses a water granulation method to form particles, whereas Habib notes that water granulation methods form particles that yield unacceptably weak tablets after compression.

In response, Habib does not teach away from any aspect of Botzolakis that is relevant to the claims at issue. Habib indicate that Botzolakis's granulation methods are unacceptable, but the claims are not drawn to methods of making. Further, Habib teaches alternatives to the granulating methods in Botzolakis that yield acceptable results. Habib does not teach away from Botzolakis as a whole, but rather offers an improvement over Botzolakis's granulation methods.

B. Habib teaches the importance of freeze-drying the cushioning component

Applicants' second argument is that the claims now specify that the composition be freeze-dried (lyophilized). According to Applicants', lyophilized cushioning components have a different structure and different physical properties from oven-dried cushioning components.

As discussed above, the evidence of record supports Applicants' factual contention that lyophilized cushioning components have a different structure and different physical properties from oven-dried cushioning components. However, because Habib also teaches that lyophilization produces the best results, the claims are still deemed obvious. Habib teaches, for example, that "[f]reeze-drying produces highly porous and compactable cushioning beads [whereas] ... other drying techniques, such as tray-drying or fluid-bed drying is [sic: are] accompanied by disadvantageous shrinking, which results in highly dense, and less compactable beads." Col. 30, lines 24-30. Habib's examples comparing freeze-dried cushioning beads to otherwise identical cushioning beads made by other drying methods support this assertion. Thus, following the teachings of Habib, the artisan would freeze-dry particles containing cushioning component, such as Botzolakis's particles which have drug surrounded by cushioning component. The artisan would do this because Habib recognizes that freeze-drying is the best method of preparing cushioning components; other methods, according to Habib, yield unacceptable results. The artisan would expect this method to work with Botzolakis's particles also, even though Botzolakis's particles have both drug and cushioning component. Freeze-drying is widely known to be an acceptable step in preparing drug compositions, so there is no reason to believe that the freeze-drying step would adversely affect the drug component of Botzolakis's particles.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Primary Examiner, Art Unit 1618